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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,398	04/20/2004	Paul E. Luner	PC25686A	4829

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EXAMINER	
AHMED, HASAN SYED	
ART UNIT	**PAPER NUMBER**
1615	
MAIL DATE	**DELIVERY MODE**
11/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/828,398	LUNER ET AL.	
	Examiner	Art Unit	
	Hasan S. Ahmed	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) *8,9 and 18-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 10-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/27/05, 1/31/05, 6/17/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicants' response to restriction requirement, which was filed on 27 August 2007.

* * * * *

Election/Restrictions

Applicant's election of Group I in the reply filed on 27 August 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 8, 9, and 18-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 27 August 2007.

* * * * *

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 3 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Specifically, at claim 3, applicants claim not more than about 2% total impurities and/or degradants when the claimed composition is stored at 40°C and 75% relative humidity for 4 weeks.

Applicants provide no evidence that they were able to achieve 2% total impurities and/or degradants under said conditions with a dry-granulated pharmaceutical composition, as claimed.

At example 2, applicants provide data of total impurities and/or degradants with a wet-granulated pharmaceutical composition. However, the level of degradant (atorvastatin lactone) achieved was much higher than that claimed, i.e. 25.4%.

As such, the instant application is not enabled for the level of total impurities and/or degradants claimed at instant claim 3.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7 and 10-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kerc, et al. (WO 02/072073) in view of Nagaprasad, et al. (WO 02/076376) further in view of Fox, et al. (WO 01/76566).

Kerc et al. teach a pharmaceutical composition comprising:

- the atorvastatin of instant claim 1 (*see* examples 3-6);

- the less than about 5 weight % of an alkaline earth metal salt additive of instant claim 2 (*see* Table 1, page 7 and Table 4, page 8);
- the unit dosage of instant claim 5 (*see* page 12, lines 11-15);
- the tablet or capsule of instant claim 6 (*see* page 12, line 13);
- the disordered (amorphous) atorvastatin of instant claim 7 (*see* abstract; page 5, lines 12-16; tables 1 and 4; page 10, lines 8-13; and examples 1-6); and
- the diluent of instant claim 10 (*see* table 1)

Kerc et al. explain that their composition is beneficial in providing therapeutic equivalence in the atorvastatin pharmaceutical formulation (*see* page 3, lines 17-23).

The Kerc et al. reference differs from the instant application in that it does not explicitly disclose the atorvastatin lactone concentrations of not more than about 2% of instant claim 4. However, the claimed level of atorvastatin lactone was achieved in the atorvastatin pharmaceutical composition art before the instant application was filed (*see* Fox, et al., example 4).

The processes dry-granulation disclosed in claim 1 is not essential to a determination of patentability of the composition disclosed in the claim. The patentability of product-by-process claims is based on the product itself. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even

though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

In any event, Nagaprasad, et al. teach a statin formulation produced by dry-granulation (*see* page 4, line 26). Nagaprasad explains that dry granulation is beneficial in producing statin formulations because it leads to greater stability (*see* page 4, lines 28-29).

While Kerc et. al. do not explicitly teach the particle sizes of instant claims 10-12, the granulation factors of instant claims 13-16, or the concentrations of instant claims 16 and 17, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to determine said parameters through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue from the claimed parameters.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a dry-granulated pharmaceutical composition comprising atorvastatin (including disordered forms of atorvastatin), low alkaline earth

metal salt additive, and low atorvastatin lactone, as taught by Kerc, et al. in view of Nagaprasad, et al., further in view of Fox, et al. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition because it results in greater therapeutic equivalence, as explained by Kerc, et al. One of ordinary skill in the art would be motivated to use a dry-granulation process because it results in greater stability, as explained by Nagaprasad.

* * * * *

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

*

1. Claims 1-7 and 10-17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of

copending Application No. 10/828,079 ('079). Although the conflicting claims are not identical, they are not patentably distinct from each other because '079 claims a composition comprising atorvastatin (claim 1) in a disordered form (claim 3), with low levels of alkaline earth metal salt additive (claim 1).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

*

2. Claims 1-7 and 10-17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of copending Application No. 10/828,419 ('419). Although the conflicting claims are not identical, they are not patentably distinct from each other because '419 claims a composition comprising atorvastatin (claim 1) in a disordered form (claim 4), with low levels of alkaline earth metal salt additive (claim 6) and atorvastatin lactone (claim 9).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

☆

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hasan S. Ahmed whose telephone number is 571-272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on 571-272-8373. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

HUMERA N SHEIKH
PRIMARY EXAMINER